STEREOTAXIS

Helios® II Ablation Catheter

REF P/N: 001-001475-1

⚠ INSTRUCTIONS FOR USE

Rx Only

HOW SUPPLIED

- The Helios II Ablation Catheter is supplied STERILE .
- The Stockert 70 RF Generator with appropriate interface cables is supplied separately.
- A grounding pad (indifferent electrode) is supplied separately.
- The Stereotaxis CAS, Cardiodrive*, and MNS are supplied separately.

SYMBOL LEGEND

REF	Catalog Number
LOT	Lot Number
	Use By
	Attention: See Instructions For Use
	Single Use
STERILE EO	Sterilized Using Ethylene Oxide
EC REP	Authorized Representative in the European Community

Manufactured under one or more of the following patents: United States, 4,869,247; 5,125,888; 5,353,807; 6,654,865; 5,707,335; 5,779,694; 5,931,818; 6,014,580; 6,015,414; 6,096,048; 6,128,174; 6,148,823; 6,152,933; 6,157,853; 6,212,419; 6,216,030; 6,241,671; 6,292,678; 6,296,604; 6,298,257; 6,304,768; 6,311,082; 6,315,709; 6,330,467; 6,352,363; 6,364,823; 6,375,606; 6,385,472; 6,401,723; 6,428 551; 6,459,924; 6,475,223; 6,505,062; 6,507,751; 6,522,909; 6,529,761
Other U.S. patents pending. Foreign patents issued and pending.

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INSTRUCTIONS FOR USE

DESCRIPTION

The Stereotaxis Helios® II Ablation Catheter is a magnetically deflectable multi-electrode device that can be used for electrophysiological mapping, pacing, and radio frequency (RF) ablations of the heart. The catheter has a highly pushable shaft with an omni-directional tip section. It is different from traditional catheters that deflect in a single plane. The catheter will deflect in any plane, and does not require applied torque for directional movement, as with conventional catheters. The tip section contains two electrodes, a 4mm platinum tip electrode which is used for making ablation lesions using radiofrequency (RF) energy and a 2 mm ring electrode, which can be used in combination with the tip electrode for stimulation and recording. To facilitate catheter deflection, three small permanent magnets are located within the distal portion of the catheter.

Tip deflection is controlled magnetically, via the Stereotaxis Magnetic Navigation System (MNS). With this system, the tip of the Helios II can be oriented in any direction, achieving a variety of tip angulations.

The catheter also incorporates a temperature sensor in the tip electrode that permits temperature monitoring during RF ablations.

The catheter interfaces with the Biosense Webster Stockert 70 RF Generator via a Biosense Webster cable model C6-MR10/MSTK-S (6 foot) or C10-MR10/MSTK-S (10 Foot)

INDICATIONS

The Helios II® Ablation Catheter is indicated for cardiac electrophysiological mapping, delivering diagnostic pacing stimuli, and for the creation of endocardial lesions to treat patients with supraventricular (SVT) tachycardias.

It is indicated to eliminate atrioventricular reentrant tachycardia (AVRT) in patients with overt or concealed accessory pathways, to eliminate AV nodal re-entrant tachycardia (AVNRT), and to create complete AV nodal block in patients with difficult to control ventricular response to atrial fibrillation.

The Helios II Ablation Catheter is indicated for use with the Biosense Webster Stockert 70 RF Generator via a Biosense Webster cable model C6-MR10/MSTK-S (6 foot) or C10-MR10/MSTK-S (10 foot).

The Helios II Ablation Catheter is for use only with the Stereotaxis Magnetic Navigation System (MNS) and is compatible with the Cardiodrive Catheter Advancement System (CAS).

CONTRAINDICATIONS

The catheter is not intended for use in the coronary vasculature, other than the coronary sinus.

Do not use this device:

- in patients with active systemic infection;
- via the transseptal approach in patients with left atrial thrombosis or myxoma, or interatrial baffle or patch;

- via the retrograde transaortic approach in patients with aortic valve replacement.

WARNINGS

This Helios II® Ablation Catheter should only be used by properly trained physicians.

Do not immerse the electrical connector or interface cable in fluids; electrical performance could be compromised.

The catheter is intended for SINGLE USE only. Do not resterilize. Reuse can compromise the catheter's performance characteristics and may result in infection.

Follow all warnings and precautions applicable to the Stereotaxis Magnetic Navigation System, especially those regarding magnetic objects (including implantable devices such as pacemakers and ICDs) in the catheter laboratory. Refer to Stereotaxis Magnetic Navigation System Operations Manual for user precautions.

Significant x-ray exposure can result in acute radiation injury as well as dose-related risk for somatic and genetic effects (dose = duration of the fluoroscopic imaging X x-ray beam intensity).

Take all appropriate measures to minimize x-ray exposure to both patients and clinical staff. Careful consideration should be given to the use of this device in pregnant women.

Stroke or myocardial infarction may occur in patients undergoing left-sided ablation procedures. Patients should be closely monitored during the postablation period for clinical manifestations of embolic events.

Implantable pacemakers and implantable cardioverter/defibrillators (ICDs) may be adversely affected by RF ablation. ICDs should be deactivated during ablation. Have temporary external sources of pacing and defibrillation available during ablation. Exercise extreme caution during ablation when in close proximity to device leads and perform a complete analysis of the implanted device function after ablation.

Complete AV block can occur when ablating septal accessory pathways or in the treatment of AVNRT. Closely monitor AV conduction during RF energy delivery and immediately terminate energy delivery if partial or complete AV block is observed. Using catheters with distal pair electrode spacing greater than 2 mm may increase the risk of AV nodal damage.

To reduce the risk of brachial plexus injury, physicians are advised to position the patient's arms inferiorly in the normal position with the hands down by the hips as opposed to superiorly.

EXPIRATION DATE

Use the device prior to the expiration date printed on the product package.

PRECAUTIONS

The Helios II Ablation Catheter is to be used only within magnetic fields created by Stereotaxis Magnetic Navigation Systems.

Do not attempt to operate the Stereotaxis Helios II Ablation Catheter prior to completely reading and understanding the applicable instructions for use.

Carefully examine the device for defects and verify proper device function and integrity.

The catheter is supplied STERILE in the unopened package. Verify that the package integrity has been maintained and that the sterility of the device has not been compromised.

The catheter is sterile and should be handled under sterile conditions. Remove the catheter carefully from the package to reduce the possibility of damaging the device.

The catheter must be stored in a cool, dry place. Storage temperature should be between 5° and 25°C (41° and 77°F)

All catheter advancement and navigation should be performed under fluoroscopic visualization.

Catheters should be stored in a cool, dry location.

The long-term risks of protracted fluoroscopy have not been established..

The long-term risks of lesions created by RF ablation have not been established. In particular, any long-term effects of lesions in proximity to the specialized conduction system or coronary vasculature are unknown.

Apparent low power output, high impedance reading or failure of the equipment to function correctly at normal settings may indicate faulty application of the dispersive electrode(s) or failure of an electrical lead. Do not increase power before checking for obvious defects or misapplication.

Catheter Compatibility

The Helios II Ablation Catheter is intended for use with the Biosense Webster Stockert 70 RF Generator via a Biosense Webster cable model C6-MR10/MSTK-S (6 foot) or C10-MR10/MSTK-S (10 foot). Refer to the Biosense Webster Stockert 70 Operations Manual for user precautions.

Read and follow the dispersive electrode manufacturer's instructions for use; the use of dispersive electrodes, which meet or exceed ANSI/AAMI requirements (HF18), is recommended.

Precautions during Catheter Use

The patient should not contact grounded metal surfaces. Use only isolated amplifiers, pacing equipment, and ECG equipment or patient injury or death may occur. Leakage current from any connected device to the patient must not exceed 10 microamps (μA) under any circumstances.

Do not use excessive force to advance or withdraw the catheter. Careful catheter manipulation must be performed in order to avoid cardiac damage, perforation, or tamponade.

Always remove or reduce the magnetic fields before attempting to remove the catheter.

Use both fluoroscopy and electrograms to monitor the advancement of the catheter to the area of the endocardium under investigation to avoid vascular or cardiac damage.

Precautions during Ablation

Do not increase power before checking for lead connection and appropriate dispersive electrode application. Effective contact between the patient and the dispersive electrode must be verified whenever the patient is repositioned.

Do not deliver RF energy with catheter outside the target site. The RF generator can deliver significant electrical energy and may cause patient or operator injury.

Avoid use of electrodes and probes of monitoring and stimulating devices, which could provide paths for high frequency current. Reduce the burn hazard by placing the electrodes and probes as far away as possible from the ablation site and the dispersive electrode.

When radiofrequency current is interrupted for either a temperature or an impedance rise (the set limit is exceeded), the catheter should be removed, and the tip cleaned of coagulum. When cleaning the tip electrode, be careful not to twist the tip electrode with respect to the catheter shaft; twisting may damage the tip electrode bond and loosen the tip electrode.

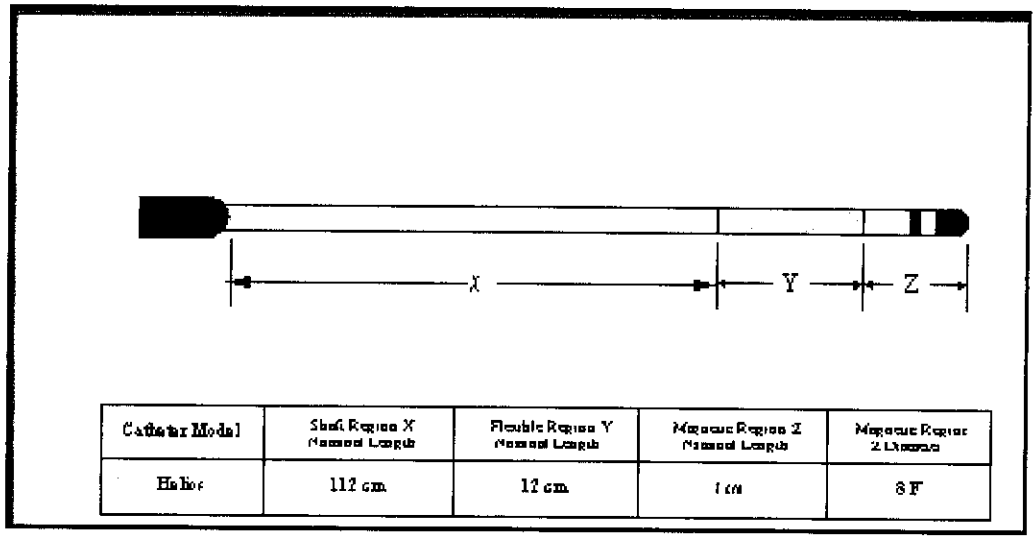
Do not scrub or twist the tip electrode as damage may cause catheter failure or patient injury.

Discontinue ablation immediately and replace catheter if tip temperature fails to rise during ablation.

The catheter measures electrode tip temperature, not tissue temperature. If the generator does not display temperature, verify that the appropriate cable is plugged into the generator. If temperature still is not displayed, there may be a malfunction in the temperature sensing system, which must be corrected before applying RF power.

Helios® II Ablation Catheter Characteristics

The shaft and tip segments nominal dimensions for the Helios® II Ablation Catheter are shown below.



Catheter Model	Shaft Region X Nominal Length	Flexible Region Y Nominal Length	Magnetic Region Z Nominal Length	Magnetic Region Z Distance
Helios	112 cm	12 cm	4 cm	8 F

Instructions for use with the magnetic navigation system

Handling and Preparation

Using aseptic technique, remove the catheter from its package and place it in a sterile working area. Inspect the catheter carefully for electrode integrity and overall condition.

Catheter use during Mapping and Ablation

1. Create a vascular access in a large central vessel using aseptic techniques. Introducers and sheaths used during the procedure should be 8.5 – 9 French in size.

2. Remove the catheter from its package within a sterile field and place it in a sterile work area.

3. Connect the catheter to the recording equipment and/or a compatible RF Generator using the appropriate interface cables.
    - Stockert 70 RF Generator - Use a Biosense Webster cable model C6-MR10/MSTK-S (6 foot) or C10-MR10/MSTK-S (10 Foot). Connect the green colored connector to the catheter and the red colored connector to the generator in the generator receptacle marked "catheter". Connect the grounding pad plug into the generator grounding pad receptacle. Refer to Biosense Webster Stockert 70 Operations Manual for proper instructions.

4. **Confirm that the magnetic fields are reduced or removed.**

5. Insert the catheter and advance it to the area of the endocardium under investigation.

6. Use the Stereotaxis Magnetic Navigation System (MNS) to orient the distal tip of the catheter, while advancing and retracting the catheter.

7. Use both fluoroscopy and electrograms to aid in proper positioning.

8. The catheter tip can be deflected to facilitate positioning by using the MNS to vary tip curvature. When it has been determined that the tip electrode is in stable contact with the intended ablation site, the catheter tip connection must be switched from the recording equipment to the RF Generator in preparation for delivery of RF current.

9. Activate ablations on the Stockert 70 generator as needed:
    - Select ablation mode (F1 for temperature control, F2 for power mode, Manual for manual mode).
    - Set desired power or temperature and time using the gray knob and/ or the arrow keys beneath the digital readouts.
    - Activate ablation cycle using the start button.
    - Ablation can be stopped at any time using the stop button.

    Refer to the Stockert 70 Instructions for further detail and diagrams.

10. **Prior to removal of the catheter, confirm that magnetic fields are reduced or removed.**

11. Remove the catheter and dispose of it in an appropriate manner. Do not resterilize and reuse.

12. If there are any questions regarding the use or performance of this product, please contact Stereotaxis Technical Support at 1-866-646-2346.

SUMMARY OF CLINICAL STUDIES

Study Overview

There were 2 clinical studies, ATTRAC and ATTRAC II, conducted to evaluate the safety and efficacy of the Helios® II Ablation Catheter for cardiac electrophysiological mapping, delivering diagnostic pacing stimuli, and for the creation of endocardial lesions to treat patients with supraventricular (SVT) tachycardias.

They were designed to study the ability of the Helios II Ablation Catheter to eliminate atrioventricular reentrant tachycardia (AVRT) in patients with overt or concealed accessory pathways, to eliminate AV nodal re-entrant tachycardia (AVNRT), and to create complete AV nodal block in patients with difficult to control ventricular response to atrial fibrillation.

Data from the ATTRAC and ATTRAC II studies served as the primary basis for the PMA approval decision. A third study (HEART) was initiated for the Helios II catheter and the Cardiodrive catheter advancement system. This study was not considered as a basis for a PMA approval decision.

Study Design

Both studies were prospective, non-randomized, unblinded, multi-center studies conducted at six U.S. clinical investigational institutions. The ATTRAC study involved 210 patients while the ATTRAC II Study enrolled 89 patients. All of the participants were age 18 and older, with at least one (1) documented tachyarrhythmia (supraventricular tachycardia; SVT) episode within the 12 months previous to study enrollment.

Efficacy endpoints

Endpoints established for assessment of device efficacy in both studies are shown in the table below.

Outcome	Success	Definition
Primary	Acute	Elimination of accessory pathway conduction. Elimination of inducible AVNRT. Complete AV block in patients who require AV node ablation.
Secondary	Long-term	Absence of recurrence of the arrhythmia (pre-excitation or AV reentrant tachycardia in patients with an accessory pathway ablation, AV nodal reentrant tachycardia in the case of patients who undergo AV nodal "slow" pathway ablation, or AV nodal conduction in the case of patients who have had AV nodal ablation) over a 90 calendar day period post-treatment.

Safety endpoints

Endpoints also established for assessment of device safety in both studies are shown in the table below.

Outcome	Success	Definition
Primary	Acute	Ablation of the target site(s) without inflicting new, acute heart injury. Comparative pre- and post-ablation echocardiograms were used to identify heart injury.
Secondary	Long-term	No excessive number of major complications within 7 calendar days of the ablation.

ADVERSE EVENTS

Potential adverse events

Anticipated or known possible adverse events associated with cardiac electrophysiology procedures include:

- Discomfort due to insertion/removal of vascular sheaths
- Hemorrhage and/or hematoma at sheath insertion site
- Extremity weakness, swelling, and/or pain
- Discomfort and/or damage to the skin, muscles, or nerves due to remaining in a supine position for an extended period of time.
- Discomfort and/or damage to the skin, muscles, or nerves due to percutaneous access
- Nausea / vomiting
- Headache
- Dyspnea or shortness of breath
- Increased or decreased blood pressure
- Brief "black out" periods
- Feeling of chest pain, skipped beats, and/or rapid heart rate
- Damage to skin from prolonged exposure to x-rays
- Atrial Fibrillation
- Arrhythmia
- Arterial injury
- Thromboembolism
- Stroke
- Transient Ischemic Attack (TIA)
- Local/systemic infection
- Pneumothorax
- AV fistula
- Thrombophlebitis
- Pulmonary embolism
- Myocardial infarction
- Complete AV block requiring pacemaker insertion
- Myocardial perforation
- Cardiac tamponade due to perforation
- Death
- Pericardial effusion
- Arterial/venous thrombosis
- Blood loss requiring transfusion
- Hemothorax
- Valvular damage (mitral or tricuspid)
- Unintended sinus node dysfunction requiring pacemaker insertion
- Pseudoaneurysm
- Vasovagal reaction
- Allergic reaction to anesthetic agent or ionic contrast
- Pericarditis
- Renal failure due to IV contrast

Observed adverse events

A total of 258 adverse events occurred in 117 patients during the ATTRAC study. The events are listed in the table below:

Adverse Event	Number of Patients Experiencing	% of Patients Experiencing
Death	1	0.5%
Vascular complications	13	7.1%
Intra-cardiac thrombus	6	3.3%
Pre-syncope/syncope	8	4.4%
Bleeding	14	7.7%
Infection	8	4.4%
CHF	2	1.1%
Arrhythmia/palpitations	17	9.3%
SOB/dyspnea/wheezing	8	4.4%
Pain (cardiac)	12	6.6%
Pain (non-cardiac)	75	41%
Hypertension	3	1.6%
Hypotension	8	4.4%
Pericardial effusion	3	1.6%
Nausea/vomiting	14	7.7
Carcinoma	2	1.1%
COPD/respiratory complications	5	2.8%
Paresthesias	1	0.5%
Edema	4	2.2%
Allergic reactions	1	0.5%
Anxiety	2	1.1%
Hernia	1	0.5%
Fatigue/weakness	5	2.8%
Fracture/sprain	1	0.5%

Major adverse events

In the ATTRAC Study there were five major adverse events that occurred within seven days of the ablation procedure that were related to the procedure. The 5 events occurred in 5 separate patients out of 182 subjects ablated with the Helios catheter (an adverse event rate of 2.7%).

One patient died during the ATTRAC study. The death was not related to either the procedure or the investigational catheter.

The table below provides a brief summary of each of the adverse events in the ATTRAC Study.

# of Events	Description
1	Linear inferior vena cava thrombus
1	Groggy (prolonged hospitalization)
1	Linear inferior vena cava clot extending into the right atrium
1	Chest soreness pain
1	Right groin pseudoaneurysm

A total of twenty (20) major adverse events occurred in 17 subjects of which 8 events were within 7 days of the investigational procedure, and 5 of which were identified as device and/or procedure-related (discussed above).

The 20 events include: 1 Death secondary to respiratory failure, 5 instances of COPD/Respiratory Complications, 2 instances of Cardiac Pain, 2 instances of Shortness of Breath/Dyspnea, 2 instances of Intra-cardiac Thrombus, 2 instances of Allergic Reactions, 1 instance of Fatigue/Weakness, 1 instance of Hypotension, 1 instance of Carcinoma, 1 instance of Hematoma/Vascular Complication, 1 instance of Infection (Pneumonia), and 1 instance of CHF. Fourteen (14) of the 20 events required hospitalization or resulted in prolongation of hospitalization due to Cardiac Pain, Fatigue/Weakness, Shortness of Breath/Dyspnea, Hematoma/Vascular Complication, Infection (Pneumonia), CHF, COPD/Respiratory Complications, and Allergic Reaction. One (1) death (Respiratory Failure) was observed 36 days following successful ablation in a subject with a history of COPD.

In the ATTRAC II Study there was one major adverse event (cardiac tamponade) that occurred within seven days of the ablation procedure that was related to the procedure. This event occurred in 1 patient out of 80 that had a Helios ® II catheter enter into the body (an adverse event rate of 1.3%).

No subjects died due to the device or procedure during the duration of the required 90-day follow-up.

PATIENT POPULATION

The table below describes the disposition of patients enrolled in both of the clinical trials.

Disposition	ATTRAC Total #	ATTRAC II Total #
Subjects enrolled	210	89
Subjects not treated with the investigational catheter	28	14
Excluded: did not meet study inclusion criteria	14	9
Discontinued: study arrhythmia could not be induced	11	5
Discontinued: equipment failure not related to the investigational devices	3	0
Subjects ablated with a Helios® Catheter	182	75
Helios® I Catheter	19	0
Helios® II Catheter	161	75
Helios® I and II Catheters	2	0

Patient Demographics

The tables below show the demographics of the patient population in both clinical trials.

ATTRAC		
Characteristic	**Total**	
Gender	**n**	**%**
Male	73	34.8%
Female	137	65.2%
Age (yrs)	**Value**	
Mean ± std dev	48.5 ± 17.0	
Min	18.1	
Max	82.4	
Subjects enrolled by arrhythmias type	**n**	**%**
Accessory Pathway	41	19.5%
AVNRT	87	41.4%
AV Node Ablation	18	8.6%
SVT	64	30.5%

ATTRAC II		
Characteristic	**Total**	
Gender	**n**	**%**
Male	29	32.6%
Female	60	67.4%
Age (yrs)	**Value**	
Mean ± std dev	52.2 ± 16.7	
Min	19.5	
Max	87.8	
Subjects enrolled by arrhythmias type	**n**	**%**
Accessory Pathway	8	9.0%
AVNRT	38	42.7%
AV Node Ablation	13	14.6%
Other	30	33.7%

STUDY RESULTS

Procedural information

The tables below summarize the procedure information for both of the clinical trials.

ATTRAC			
Procedure Information	**Mean**	**Med**	**Min**
Procedure time (hrs)	3.2 ±_2.4	2.5	0.2
Total imaging time (min)	15.9 ±13.1	12.1	1.1
Ablation time (min)	38.5 ±_41.5	26.0	0
Number of energy applications	9.7 ±_8.8	7	1
Maximum impedance (ohms)	118.6 ±_98.4	112	78
Maximum temperature (°C)	51.5 ±_8.2	50	10
Maximum watts (watts)	36.7 ±_11.6	38	5
Duration (sec)	37.8 ±_28.7	30	0

ATTRAC II			
Procedure Information	**Mean**	**Med**	**Min**
Procedure time (hrs)	2.3 ± 1.2	2.1	0.3
Total imaging time (min)	11.3 ± 10.1	8.8	0.6
Ablation time (min)	37.1 ± 49.2	20.0	1.0
Number of energy applications	13.3 ± 15.5	6.0	1.0
Maximum impedance (ohms)	110.9 ± 25.1	105.0	69.0
Maximum temperature (°C)	57.5 ± 88.4	50.0	5.0
Maximum watts (watts)	40.8 ± 55.5	38.0	3.0
Duration (sec)	31.9 ± 25.6	24.0	1.0

Antiarrhythmic drugs

In the ATTRAC Study, 128 patients out of 147 (87.1%) included in the long term follow-up analysis were able to discontinue use of AADs following ablation treatment. The 19 patients who continued to use AADs can be attributed to cardiac conditions other than those treated under this study.

In the ATTRAC II Study, 48 patients out of 54 (88.9%) included in the long term follow-up analysis were able to discontinue use of AADs following ablation treatment.

Ablation Results

The acute overall success rate for patients treated with the Helios II Ablation Catheter in the ATTRAC Study was 96.2% (175/182). The overall chronic success rate for all patients experiencing an absence of arrhythmia recurrence for over 90 days was 98.6% (145/147). These efficacy results for the Helios II Ablation Catheter are summarized in the table below.

The acute overall success rate for patients treated with the Helios II Ablation Catheter in the ATTRAC II Study was 94.7% (71/75). The overall chronic success rate for all patients experiencing an absence of arrhythmia recurrence for over 90 days was 94.4% (51/54). These efficacy results for the Helios II Ablation Catheter are also summarized in the table below.

	ATTRAC		ATTTRAC II	
Helios II Ablation Results	**Success Rate**	**95% LCB**	**Success Rate**	**95% LCB**
Acute success: • Successful ablation of the target sites • Success rate defined as >96.9%	96.2%	(92.2%)	94.7%	(86.9%)
Chronic success: • Absence of recurrence of the arrhythmia over 3 months • Success rate defined as >93%	98.6%	(95.2%)	94.4%	(84.6%)

CI = Confidence Interval

Safety Results

Two (2) patients out of 177 (1.1%) who received a post-ablation echocardiogram in the ATTRAC Study reported acute heart injury. The long-term safety results showed 5 of 182 (2.7%) patients reporting major adverse events within 7 days of ablation. These results are summarized in the table below.

One (1) patient out of 69 (1.4%) who received a post-ablation echocardiogram in the ATTRAC II Study reported acute heart injury. The long-term safety results showed 1 of 80 (1.3%) patients that had a Helios® II catheter enter the body reported a major adverse events within 7 days of the procedure. These results are also summarized in the table below.

	ATTRAC		ATTRAC II	
Helios II Safety Results	**Rate**	**95% CB**	**Rate**	**95% CB**
Acute Safety: • Ablation of the target site(s) without inflicting new, acute heart injury. • Success rate defined as <1.3%	1.1%	(4.0%)	1.4%	(7.8%)
Long-Term Safety: • No excessive number of major complications within 7 calendar days of the ablation. • Success rate defined as <2.0%	2.7%	(6.3%)	1.3%	(6.8%)

CB = Confidence Boundary

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